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Anthony Toranto

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EXAMINER

COOK, LISA V

ART UNIT

PAPER NUMBER

1641

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 09/976,872 | Applicant(s) TORANTO ET AL. | |
| | Examiner LISA V. COOK | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 02 July 2008.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1,3-8 and 10-15 is/are pending in the application.

 4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1,3-8 and 10-15 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's response to the Office action mailed 4/2/08 is acknowledged (paper filed 7/2/08). Applicant's amendment filed therein is also acknowledged. Claim 1 was modified. Claims 2, 9 and 16-74 have been canceled. Accordingly, claims 1, 3-8, and 10-15 are pending and under consideration.
2. Rejections and/or objections of record not reiterated herein have been withdrawn.

NEW GROUNDS OF REJECTIONS NECESSITATED BY AMENDMENT

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Oath/Declaration

4. A new oath or declaration is required because the date is not included for inventor Evan Singer (see Oath filed 7/2/08). Appropriate correction is required. The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required.

Art Unit: 1641

The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Claim Objections

5. Claim 11 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. In particular, claim 11 is dependent on canceled claim 2. It is suggested that claim 11 depend from claim 1. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Appropriate correction is required. For the purpose of examination claim 11 has been treated as dependent on claim 1.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 1, 3-5, 8, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) in view of Titmas (US Patent #5,563,073).

Sangha discloses a method of collecting, identifying, and quantifying saliva. The presence of the peroxidase enzyme (an analyte) in saliva is reacted with a peroxide to oxidize the "leuco" or colorless form of a dye or other indicator and produce a colored reaction for measurement (claim 1). See column 4 lines 22. In a second enzymatic method for verifying the presence of saliva a free colored chromagen that is visible to an observer is produced (claim 11). See column 4 lines 23-34.

Various colored chromagens may be utilized in the invention. See column 6 lines 1-25. The use of the color indicators in the collection probe of this patent allows for confirmation of saliva collection as well as sample collection amounts. See abstract and column 4 lines 19-22.

In one embodiment, a swab is placed in the mouth of a subject and collected. The swab is then transferred to application zones onto an absorbent layer. See column 5 lines 44-54. The saliva sample is collected on a sample probe comprising a support stick with an absorbent attached to one end of the support (claims 3 and 4). This has been interpreted to read on Applicant's test strip as defined by the specification on page 16 line 26 through page 17 line 2 wherein "the test assay" comprises a simple test strip containing a reactive site at one end," and exemplified in figure 18.

In alternative procedures the entire swab comprising the reaction site is placed in the subject's mouth. "the entirety of absorbent 54 may be inserted into the mouth of the subjectfor collection of saliva thereon." See column 8 lines 54-57 and figures 4-6. Absorbent 54 including a test portion 58 having an indicator component. See column 8 lines 65-68 for example. The indicator reads on applicant's claimed reaction site as taught on column 4 lines 14-22.

Although Sangha disclose the measurement of the peroxidase enzyme found in saliva they are silent with respect to the use of potassium iodide. However, this is deemed inherent to the teachings of Sangha because potassium iodide is a known substrate for peroxidase activity in saliva. This is evidenced by the English abstract to Levitskii et al. In addition, Sangha discloses the utility of iodide ions in column 12 line 50, which encompasses the potassium iodide of the instant claims.

Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) differ from the instant invention in failing to particularly teaching that the analyte comprises an alcohol moiety (i.e. analyte is ethanol) that is reactive with an enzyme, wherein the measured concentrations are indicated by a color change of 0.04% blood alcohol concentration.

Art Unit: 1641

Titmas teaches a personal blood alcohol level testing kit. The kit includes pads (strips) with at least one alcohol-sensitive enzyme (i.e. alcohol oxidase enzyme and alcohol peroxidase enzyme), at least one dye, and at least one buffer. For example, see column 6 line 10-11. The pad changes color when it is contacted with saliva containing alcohol. See column 2 lines 61-67. The measurement of alcohol level in saliva is taught to be approximately 98% accurate. See column 2 line 2. The pads can be placed into the mouth for saturation or dipped into a collection cup. see column 3 lines 36-45.

Although Titmas is silent with respect to ethanol and glucose detection, the patent teaches alcohol measurements which encompass ethanol and glucose (or the sugar alcohols).

Titmas teaches that an alcohol sensitive pad that noticeably changes colors at blood alcohol levels of 0.04% and 0.08% by volume blood alcohol levels may be desirable because Federal law sets the limit for drunk driving at 0.04% by volume blood alcohol and most states set the limit for drunk driving at 0.08% by volume blood alcohol. Thus the color change at these alcohol levels will easily inform the user that they are considered by either Federal or state law to be a drunk driver (intoxicated). See column 6 lines 45-53.

It would have been obvious to one of ordinary skill in the art at the time of the invention to detect alcohol blood concentrations with an enzymatic testing pad with a color change at 0.04% blood alcohol levels as taught by Titmas in the saliva testing method of Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) because Titmas taught that the measurement of alcohol levels in saliva is approximately 98% accurate. See column 2 line 2. The enzymatic reaction pads in Titmas utilized alcohol sensitive pads that noticeably changes color at blood alcohol levels of 0.04% and 0.08% by volume blood alcohol levels. These levels are set by Federal law and state laws for drunk driving. Thus the color change at these alcohol levels would easily inform the user if they are considered by either Federal or state law to be a drunk driver (intoxicated). See column 6 lines 45-53.

One of ordinary skill in the art would have been motivated to measure their blood alcohol level in order to prevent injury from being intoxicated or arrests for driving under the influence of alcohol.

II. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) in view of Titmas (US Patent #5,563,073) and further in view of Spring et al. (US Patent #5,643,721).

Art Unit: 1641

Please see Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) in view of Titmas (US Patent #5,563,073) as set forth above.

Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) in view of Titmas (US Patent #5,563,073) differ from the instant invention in failing to particularly teach the reaction site comprising a biosensor.

However, Spring et al. teach biosensors comprising immobilizing mediums (test strips). See abstract and column 8 through column 11. The immobilizing mediums comprise the appropriate bioreagents and is useful in any assay format. See column 2 lines 51-67 for example. The biosensors can be employed with various "test samples", including saliva. See column 4 lines 61-67.

The immobilization medium taught by Spring et al. can be employed for the preparation of biosensor devices, in which the reaction of the enzyme substrate is monitored directly by an electrochemical or optical sensor. See column 11 section V.

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the reaction site (immobilizing medium) of Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) in view of Titmas (US Patent #5,563,073) into the biosensor of Spring et al. because Spring et al. taught that his sensor allowed for direct assay measurement with an electrochemical or optical sensor. See Spring et al. column 11 section V.

Art Unit: 1641

One of ordinary skill in the art would have been motivated to employ biosensors in order to generate precise and accurate data for the analyte of interest.

III. Claims 6 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) in view of Titmas (US Patent #5,563,073) and further in view of Bogema (US Patent #6,248,598).

Please see Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) in view of Titmas (US Patent #5,563,073) as set forth above.

Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) in view of Titmas (US Patent #5,563,073) differ from the instant invention in failing to particularly teach an antibody in the reaction site and the amount of time the reaction site should be held in a patient's mouth in order to generate a detectable signal.

However, Bogema teaches a test strip device that can be utilized to measure at least one analyte in saliva samples. The device allows for the simple collection and simultaneous analysis of saliva without the need for saliva manipulation or the use of instrumentation outside of the device. See column 3 lines 30-39, for example.

Bogema teaches that combining the collection of specimen and the analysis into a single device with no operations or reagents will greatly simplify the test and allow untrained users to perform the collection and analysis. See column 3 lines 51-54. The device can be composed of various binding partners including antibodies (claim 6). See column 9 lines 34-38. A portion of the solid support (strip) includes a visual reading area on which is directly bound a binding partner, a protein such as an antibody that specifically binds an analyte that comprise of a colored label (col. 8, lines 12-23). The results can be seen with the naked eye (col. 8, lines 52-54).

The device comprises a solid support (strip) with suitable absorbent material which is inserted into a patient's mouth for about 10-120 seconds to absorb saliva (claims 12 and 14-15). See column 7 lines 15-65.

It would have been obvious to one of ordinary skill in the art at the time of the invention to place the reaction site in a subject's mouth from about 10 to 120 seconds as taught by Bogema into the saliva analysis method of Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) in view of Titmas (US Patent #5,563,073) because Bogema taught that his device allows for the simple collection and simultaneous analysis of saliva without the need for saliva manipulation or the use of instrumentation outside of the device. See column 3 lines 30-39, for example.

Art Unit: 1641

Bogema teaches that combining the collection of specimen and the analysis into a single device with no operations or reagents will greatly simplify the test and allow untrained users to perform the collection and analysis. See column 3 lines 51-54.

With respect to the detectable signal being generated faster than 5 seconds in the subjects mouth (claim 13), it is noted that Bogema discloses a time frame from *about* 10 seconds (reading on less than 5 seconds). See column 7 lines 15-65. Absent evidence to the contrary it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to optimize the time of signal detection in order to generate rapid results.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments and amendments have been carefully considered and found persuasive. New rejections have been applied accordingly.

In particular, Applicant contends that claims 1-4 and 11 are not anticipated by Sangha as evidence by Leviskii et al. This argument along with Applicant's amendment was found persuasive. The anticipation rejection under 102 (b) has been withdrawn.

New rejections under 35 USC 103 (a) are presented herein. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant contends that Sangha does not teach the exposure of the assay test reaction site into the subject's mouth. This argument has been carefully considered but not found persuasive because in alternative procedures the entire swab comprising the reaction site is placed in the subject's mouth. "the entirety of absorbent **54** may be inserted into the mouth of the subjectfor collection of saliva thereon." See column 8 lines 54-57 and figures 4-6. Absorbent **54** including a test portion **58** having an indicator component. See column 8 lines 65-68 for example. The indicator reads on applicant's claimed reaction site as taught on column 4 lines 14-22.

The test for obviousness is not whether the features of one reference may be bodily incorporated into the other to produce the claimed subject matter but simply what the combination of references makes obvious to one of ordinary skill in the pertinent art. See *In re Bent*, 52 CCPA 850, 144 USPQ 28 (1964); *In re Nievelt*, 179 USPQ 224 (CCPA 1973).

Also, a reference is not limited to its working examples, but must be evaluated for what it teaches those of ordinary skill in the art. *In re Boe*, 355 F.2d 961, 148 USPQ 507 (CCPA 1966). *In re Chapman*, 357 F.2d 418, 148 USPQ 711 (CCPA 1966).

Art Unit: 1641

Further, it is noted that KSR forecloses the argument that a **specific** teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith*, --USPQ2d--, slip op at 20, (Bd. Pat. App. & Interf. June 25, 2001) (citing *KSR*, 82 USPQ 2d at 1396)(available at <http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf>).

7. For reasons aforementioned, no claims are allowed.
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1641

9. The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, can be reached on (571) 272-0806.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Art Unit: 1641

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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